# FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

***Peripheral and Central Nervous System Drugs Advisory Committee Meeting***

The Inn and Conference Center, University of Maryland University College (UMUC)
Marriott Conference Centers
3501 University Blvd. East, Adelphi, MD

QUESTIONS TO THE ADVISORY COMMITTEE

OCTOBER 14, 2009

1. Has the sponsor demonstrated substantial evidence of effectiveness of fampridine as a treatment to improve walking in patients with multiple sclerosis (MS)? YES/NO/ABSTAIN

    a. If yes, has the sponsor demonstrated that this effect is clinically meaningful, either in the group of fampridine-treated patients as a whole, or in a specific subset? DISCUSSION

2. If yes to question #1, should the sponsor be required to evaluate the effects of doses lower than 10 mg twice daily (BID)? YES/NO/ABSTAIN

    a. If yes, should this be required prior to approval? YES/NO/ABSTAIN

3. If substantial evidence of a clinically meaningful effect has been demonstrated, do you conclude that there are conditions under which fampridine could be considered safe in use for this indication? YES/NO/ABSTAIN

    a. If yes, what are those conditions (e.g., specific enrollment criteria, specific monitoring, etc.)? DISCUSSION